

REMARKS

This Response is responsive to the Office Action dated January 9, 2009. In this Response, Applicant has not amended the claims. Claims 1-9, 11-31, and 33-36 remain pending.

Allowable Subject Matter

In the Office Action, the Examiner indicated that claims 19-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant appreciates the Examiner's indication of allowable subject matter and agrees with the Examiner that claims 19-26 would indeed be allowable if rewritten in independent form, as suggested.

Claim Rejection Under 35 U.S.C. § 103

Claims 1-3, 5, 7-9, 27-29, 31 and 34-36

In the Office Action, the Examiner rejected claims 1-3, 5, 7-9, 27-29, 31 and 34-36 under 35 U.S.C. 103(a) as being unpatentable over Cigaina (US 5,423,872) in view of Douglas (US 5,292,344).

Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested a rational reason to arrive at the claimed invention.

Independent claim 1 recites a system for gastric stimulation of a patient comprising a plurality of sensing electrodes for sensing intrinsic gastric activity from a stomach wall of a patient, and an implantable gastric stimulator coupled to the sensing electrodes, the implantable gastric stimulator receiving the sensed intrinsic gastric activity and performing an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determining whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal. Per claim 1, the implantable gastric stimulator delivers the electrical stimulation when the sensed intrinsic gastric activity is classified as normal. The system further comprises a plurality of stimulation electrodes configured to convey the electrical stimulation from the implantable gastric stimulator to the

Accordingly, contrary to the Examiner's statement, claim 1 requires more than simply identifying electrical activity and providing "on-demand" stimulation.

In addition to the shortcomings in the Examiner's characterization of the features of the independent claim 1, the applied references fail to teach or suggest a system that performs an analysis of sensed intrinsic gastric activity to classify the activity as normal or abnormal, determines whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal, and delivers the electrical stimulation when the sensed activity is classified as normal, as recited by independent claim 1.

Cigaina generally describes a process that consists of artificially altering, by means of sequential electrical pulses and for preset periods of time, the natural gastric motility of a patient and/or the time and manner of contraction of the lower esophageal and pyloric sphincters to prevent emptying or to slow down gastric transit or prevent duodenal acidification during interdigestive phases or to prevent gastric reflux in the last portion of the esophagus.¹ In particular, Cigaina describes an electrical stimulator that 1) induces antral tachygastria in order to slow down or prevent gastric transit through the pylorus into the intestine located downstream and thus allow treatment of obesity related to hyperalimentation; 2) modulates fasting gastric hypermotility for the treatment of relapsing duodenal ulcer in anxious subjects; or 3) improves the functionality of the lower esophageal and/or pyloric sphincters in treating reflux esophagitis and gastropathy induced by duodenogastric reflux.² As identified by the Examiner, Cigaina generally describes that "[t]he stimulator can be programmed for both continuous stimulation and for 'on demand' stimulation, i.e., at the onset of a particular electrical activity which can be detected by the stimulator itself through the electrocatheter."³

However, nowhere does Cigaina teach or suggest a system configured to analyze sensed intrinsic gastric activity to classify the activity as normal or abnormal, much less deliver the electrical stimulation, which is configured to disrupt normal gastric activity of the stomach, when the sensed activity is classified as normal, as required by claim 1. Instead, Cigaina merely describes an electrical stimulator that delivers electrical stimulation to alter the natural gastric motility of a patient in the manner described above, and that the stimulator may be programmed

¹ Cigaina, col. 2, line 67 through col. 3, line 7.

² Cigaina, col. 3, lines 20-30.

³ Cigaina, col. 3, lines 41-45.

stomach wall of the patient when the sensed intrinsic gastric activity is classified as normal. Per claim 1, the electrical stimulation is configured to disrupt normal gastric activity of the stomach.

In the Office Action, with regard to independent claims 1, 29, 35 and 36, the Examiner stated (at Item 4) that:

Cigaina discloses a gastric pacemaker that senses electrical activity and then provides “on demand” stimulation (Col. 3, ll. 41-45). Cigaina further discloses that the system stimulates to disrupt normal slow waves and prevent emptying of the stomach.

The Examiner further stated (at Item 6) that “Cigaina discloses a system that senses and then disrupts normal activity, [but] it is silent as to if the gastric pacemaker includes multiple electrodes.” However, in view of this deficiency, the Examiner further stated that:

Douglas discloses a gastric pacemaker that includes multiple electrodes for sensing and stimulating that are located through the stomach and connected to sensing and stimulation channels (Figs. 1 & 2A). Douglas further teaches how the electrodes are connected to the gastric pacemaker on one end and the stomach wall on the other end (FIG. 2A).

On this basis, the Examiner reasoned that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the gastrointestinal pacemaker of Cigaina with the multiple-electrode gastrointestinal pacemaker of Douglas in order to provide the predictable results of increasing the sensing and stimulation sites to provide increased control.

Applicant respectfully disagrees with the Examiner’s characterization of the features of the independent claims and the conclusion of obviousness with respect to the applied references.

For example, in addressing independent claim 1, the Examiner asserted that Cigaina describes a device that senses electrical activity and then provides “on-demand” stimulation to disrupt normal activity and prevent emptying of the stomach. However, regardless of whether or not Cigaina actually describes a device as characterized by the Examiner, independent claim 1 requires more than sensing electrical activity and providing “on-demand” stimulation to disrupt normal activity. Instead, independent claim 1 requires, *inter alia*, a system which receives sensed intrinsic gastric activity from the stomach wall of a patient, performs an analysis of the sensed intrinsic gastric activity to classify the electrical gastric activity as normal or abnormal, and delivers electrical stimulation when the sensed electrical gastric activity is classified as normal. Per claim 1, the electrical stimulation created when the sensed electrical gastric activity is classified as normal is configured to disrupt normal gastric activity of the stomach.

for “on-demand” stimulation (i.e., at the onset of a particular electrical activity detected by the stimulator).

While Cigaina does appear to describe initiating stimulation at the onset of a particular electrical activity detected by the stimulator, Cigaina fails entirely to provide any details as to the nature of the particular electrical activity detected by the stimulator. Indeed, Cigaina does not describe what particular type of electrical activity detected by the stimulator triggers the delivery of one or more types of stimulation, or even if the electrical activity that triggers stimulation is unique to the specific type of stimulation delivered to the patient. Regardless, Cigaina fails to disclose that the stimulator analyzes the sensed electrical activity to classify the electrical activity as normal or abnormal, much less a stimulator that then delivers the electrical stimulation when the sensed activity is classified as normal

Even assuming arguendo that the stimulator of Cigaina may be configured to deliver electrical stimulation to induce antral tachygastria upon detecting particular electrical activity indicative of food entering a patient stomach, for example, Cigaina still would fail to teach or suggest analyzing sensed intrinsic gastric activity to classify the gastric activity as normal and abnormal. Instead, in such a configuration, the Cigaina stimulator would appear to classify sensed electrical activity as being either indicative of food entering the stomach or not indicative of food entering the stomach, rather than whether the electric gastric activity is abnormal or normal.

For at least the reasons outlined above, Cigaina fails to teach or suggest the features of independent claim 1. Moreover, Douglas fails to provide any teaching sufficient to overcome the deficiencies identified in Cigaina. Accordingly, the Examiner has failed to establish a prima facie case for non-patentability of claim 1 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Independent claim 29, recites a method for gastric stimulation of a patient comprising sensing intrinsic gastric activity on the stomach wall of a patient; classifying the sensed intrinsic electrical gastric activity as normal or abnormal, determining when to apply electrical stimulation to the stomach wall of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal, and applying the electrical signal to disrupt normal gastric activity of the stomach.

For at least the reasons previously identified with regard to claim 1, the applied references fail to teach or suggest the features of independent claim 29. For example, the applied references fail to teach or suggest classifying sensed intrinsic electrical gastric activity as normal or abnormal and determining when to apply electrical stimulation to the stomach wall of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, much less forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal and applying the electrical signal to disrupt normal gastric activity of the stomach, as required by claim 29.

Independent claim 35 recites a system comprising a plurality of sensing electrodes for sensing intrinsic electrical gastric activity from a stomach wall of a patient; an implantable gastric stimulator coupled to the sensing electrodes, wherein the implantable gastric stimulator receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal, and wherein the stimulator creates electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal; and a plurality of stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient, the electrical stimulation being configured to disrupt normal gastric activity of the stomach.

For at least the reasons previously identified with regard to claims 1 and 29, the applied references fail to teach or suggest the features of independent claim 35. For example, the applied references fail to teach or suggest a stimulation that receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal, much less that the stimulator creates electrical stimulation, which is configured to disrupt normal gastric activity of the stomach, when the sensed intrinsic electrical gastric activity is classified as normal, as required by claim 35.

Independent claim 36 recites a method comprising sensing intrinsic electrical gastric activity from a stomach wall of a patient, classifying the intrinsic electrical gastric activity as normal or abnormal, applying electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal, wherein the electrical stimulation is configured to disrupt normal gastric activity of the stomach, and withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal.

For at least the reasons previously identified with regard to claims 1, 29, and 35, the applied references fail to teach or suggest the features of independent claim 36. For example, the

applied references fail to teach or suggest sensing intrinsic electrical gastric activity from a stomach wall of a patient, and classifying the intrinsic electrical gastric activity as normal or abnormal, much less applying electrical stimulation, which is configured to disrupt normal gastric activity of the stomach, to the patient when the intrinsic electrical gastric activity is classified as normal, as required by claim 36.

Moreover, the applied references fail to teach or suggest withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal, as required by claim 36. By applying the electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal and withholding electrical stimulation when intrinsic electrical gastric activity is classified as abnormal, such a technique may ensure that normal intrinsic electrical activity of a patient is disrupted without unnecessarily delivering electrical stimulation to the patient when abnormal electrical activity of is sensed.

Claims 2, 3, 7-9, 27, 28, 31 and 34 are all either directly or indirectly dependent on independent claim 1 or 29. As such, each of the dependent claims includes the limitations of the corresponding independent claim. For the reasons previously stated, the applied references fail to teach or suggest the features of independent claims 1 and 29 and, therefore, do not teach or disclose all features of claims 2, 3, 7-9, 27, 28, 31 and 34.

In addition to the deficiencies identified with respect to independent claims 1 and 29, the applied references also fails to teach or suggest the features of the various dependent claims. For example, the applied references fail to teach or suggest analyzing the sensed intrinsic gastric activity and classifying the sensed intrinsic gastric activity as a slow wave or a peristaltic wave, as required by dependent claims 9 and 31.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-3, 5, 7-9, 27-29, 31 and 34-36 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Claims 4, 6, 11-18 and 30

The Examiner also rejected claims 4, 6, 11-18 and 30 under 35 U.S.C. 103(a) as being unpatentable over Cigaina in view of Douglas as applied to claims 1 and 7 above, and further in view of Gordon (US 6,895,278).

Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Dependent claims 4, 6, 11–18 and 30 are all either directly or indirectly dependent on independent claim 1 or claim 29. As such, the dependent claims include the limitations of their respective independent claim. For the reasons previously stated, Cigaina and Douglas, viewed in combination or individually, do not disclose or suggest all features of independent claims 1 and 29 and, therefore, does not teach or disclose all features of claims 6, 11–18 and 30. Furthermore, these identified deficiencies are not overcome by the teachings of Gordon.

In addition, Gordon, in combination with Cigaina and Douglas, also fails to teach or suggest the features of the various dependent claims. For example, the applied references fail to teach or suggest the feature of the stimulator temporarily reverting to a power conserve condition in the absence of a programmable threshold of normal activity, as required by claim 11. While Gordon describes using a programmable calendar 48 in FIG. 3 to provide increased stimulation at certain hours of the day, and decreased stimulation at other hours of the day, the specific times of providing decreased stimulation appear to be preprogrammed times based on when gastric activity is estimated to be less than other times of the day.⁴ On the contrary, claim 11 requires that the stimulator revert to a power conservation condition in the absence of a programmable threshold of normal activity, rather than preprogrammed time periods as described by Gordon.

As another example, the applied references fail to teach or suggest the features of dependent claim 14–18. Indeed, the applied references fail to teach or suggest that: the electrical stimulation is delivered across the sensed intrinsic gastric activity, as required by claim 14; the electrical stimulation is delivered with a spatial offset to the sensed intrinsic gastric activity, as required by claim 15; the electrical stimulation is delivered with a temporal offset to the sensed intrinsic gastric activity, as required by claim 16; or the electrical stimulation is delivered in anticipation of the next normal electrical activity, as required by claim 17.

Applicant respectfully notes that the Office Action failed to address the various features of dependent claims 14–18. Applicant respectfully requests that the Examiner provide support for the rejection of dependent claim 14–18 as obvious over the applied references, or withdraw the rejection of claims 14–18.

⁴ See Gordon, column 10, line 44 to column 11, line 41.

As another example, contrary to the Examiner's argument, Gordon fails to teach or disclose maintaining a history of predecessor electrical events, as required by claim 30. While Gordon describes a device including a memory provided to store data,⁵ Gordon makes no mention of maintaining a history of predecessor events, much less predecessor electrical events.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 6, 11-18 and 30 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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5/11/09

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⁵ Gordon, column 5, lines 1-3.